d.) Remarks.

Currently claims 11, 29-30 and 33-47 are pending.

Remarks Regarding 35 U.S.C. § 103(a)

Claims 11, 29, 30 and 33-47 stand rejected, under 35 U.S.C. § 103(a), as allegedly obvious over Shih et al. (U.S. patent No. 4,026,767; "Shih") in view of Litman et al. (U.S. Patent No. 4,374,925; "Litman"). Applicant respectfully traverses this rejection.

The Applicant respectfully traverses the Examiner's rejection and asserts that a person skilled in the art having regard to the cited references would not be led directly and without difficulty to the claimed subject matter for the reasons set forth below. Accordingly, the Applicant asserts that such a person would not regard the claimed subject matter as obvious in light of the cited references.

In addition, Applicant respectfully asserts that the claimed invention is indeed surprising and unexpected, as evidence by the Examiner's comments in the Office Action. In the instant Office Action the Examiner states that it would have been *prima facie* obvious to apply Litman's "*digestion, incubation, conjugation and detection to an effective method of detecting 10,000 cfu/ml or less of bacteria as taught by Shih*" (see Office Action, page 5, last paragraph). This is clear upon noting that the principal reference was filed in 1975, nearly 32 years prior to today and 26 years prior to the filing date of the instant application. Further, the secondary reference, Shih, was filed 20 years prior to the filing date of the instant application. Applicant respectfully asserts that competition in the field of the claimed invention is intense and has been for many years. For at least this reason it is inconceivable that that two references that are each over 20 years old could suggest the claimed invention. Even if, *arguendo*, the references do contain all of the elements as set forth in Applicant's claims, only Applicant was able to combine the necessary aspects and obtain the superior results achieved with the claimed process. Thus, for these reasons alone the claims cannot be considered obvious. The rejections would also be moot as Applicant's process must be surprising and unexpected as the two references are each over 20 years old.

In addition, as set forth previously, Shih is unrelated to the claimed invention. This reference is directed to the detection of microorganisms in whole blood by colormetric determination (Shih column 1, lines 4-7). A nutrient medium containing a tetrazolium salt is converted to a blue color in response to dehydrogenase formed in the nutrient medium in the

presence of microorganisms in the blood (Shih column 1, lines 61-67). However, unlike the claimed invention, Shih does not disclose digestion of the microorganisms or the use of antibodies to detect viability markers accumulated in the microorganisms. These aspects are also absent from Litman.

Moreover, the instant application is directed to increasing the speed of detection to less than eight hours. Shih does not disclose or suggest a method capable of decreasing the detection time, or increasing the sensitivity of detection, so drastically as the claimed invention. The Office Action is able to point to merely one cursory mention of speed of detection in Shih, at column 5, line 28, in which only an unspecific assertion of Shih's test being able to be performed "quickly" is present. The Office Action is also not able to point to a single passage which discloses or suggests the claimed 10,000 cfu/mL or less detection anywhere in Shih, because no such suggestion or disclosure exists.

Although increased sensitivity and speed of detection methodologies is a pervasive goal in scientific research, the fact that problems exist and may be allegedly generally known or even identified does not make the resolution of such problems obvious, particularly in fields in which researchers are constantly striving for improved methodologies. The claimed invention provides exponential amplification of sensitivity and speed of detection for microorganisms, which are not suggested or disclosed by the prior art, particularly as the cited references had proved to be incapable of solving these existing problems.

Finally, the Applicant asserts that neither Shih nor Litman, alone or in combination, achieve the same levels of sensitivity (detection of 10,000 cfu/mL or less of microorganisms) as does the claimed invention, and neither Shih nor Litman, alone or in combination, disclose or suggest the methods for achieving sensitivity of the claimed invention. Although the Examiner points to an assertion of an enzyme to which an antibody binds in Litman, the Office Action's equating Litman's enzymes to Applicant's viability markers on cell fragments of digested microorganisms is erroneous. Specifically, neither Shih nor Litman disclose or suggest employing digestion reagents comprising, for example, lysosome, to *digest* the microorganisms which have been marked with a viability substrate to produce marked cell debris, which is then detected (see specification pages 9-10).

It is at least this extra unique step of digesting microorganisms to produce cell fragments with viability markers adsorbed to the surfaces of cellular debris which contributes to the marked improvement of sensitivity achieved by the claimed invention.

For at least the reasons set forth above and in Applicant's prior Responses, the claims are not disclosed or suggested by the combination of references cited by the Examiner.

Applicant respectfully requests that the rejection of claims 11, 29, 30 and 33-47, under 35 U.S.C. § 103(a), be withdrawn as overcome or considered moot in view of Applicant's superior and unexpected results.

Conclusion

In view of the foregoing remarks, reconsideration of the application and issuance of a Notice of Allowance is respectfully requested. If there are any issues remaining which the Examiner believes could be resolved through either a Supplemental Response or an Examiner's Amendment, the Examiner is respectfully requested to contact the undersigned at the number below.

Should additional fees be necessary in connection with the filing of this Responsive Amendment, or if a petition for extension of time is required for timely acceptance of same, the Commissioner is hereby authorized to charge **Deposit Account No. 14-1437, referencing Attorney Docket No. 8109.003.USDV, for any such fees**; and Applicant hereby petitions for any needed extension of time not otherwise accounted for with this submission.

Respectfully submitted,
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Date: September 17, 2007

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